

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
JOHN D. PUSKAS)
Serial No. **Not Assigned**) Examiner:
Filed: **Concurrently Herewith**) Art Unit:
For: **METHODS OF INDIRECTLY**)
STIMULATING THE VAGUS NERVE)
WITH AN ELECTRICAL FIELD)

PRELIMINARY REMARKS

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examining the application identified above, please consider the following remarks:

REMARKS

Summary of the Claims and Support Therefor

The newly added claims all relate to methods for stimulating a vagus nerve by means of an electric field generated by one or more electrodes. Claims 1–15 relate to stimulating a vagus nerve by one or more electrodes located in the esophagus. Support for Claim 1 is found in the specification, *e.g.*, at page 8, lines 5–19, which discloses electrical stimulation of a vagus nerve (“stimulation of the right or left vagus”) by inserting a catheter having an electrode located thereon (“stimulation with a percutaneous catheter or electrode probe”) into

the esophagus of the patient (“stimulation … in the internal jugular vein, esophagus, or trachea”) (emphasis added).

Claim 2 is dependent upon Claim 1 and adds the additional limitation of a second electrode in the esophagus in spaced-apart relation to the first electrode. Claim 3 adds the limitation that the two electrodes are spaced approximately 1 cm apart. Claim 4 is dependent from Claim 2 and adds the limitation that both electrodes are actuated. Support for Claims 2–4 is found in the specification, *e.g.*, at page 8, lines 5–19 (“other suitable stimulators include a pair of pacing wires or electrodes placed about 1 cm apart”).

Claim 5 recites that the electrodes may be actuated in either unipolar or bipolar mode. Support is found in the specification, *e.g.*, at page 8, lines 5–19 (“Other suitable locations for vagus nerve stimulation include … unipolar or bipolar electrical stimulation”).

Claim 6 is dependent from Claim 1 and recites that the vagus nerve is stimulated for a period of between about five and about ninety seconds. Claim 7 is dependent from Claim 6 and limits the period of stimulation to 5 to 15 seconds. Support is found in the specification, *e.g.*, at page 8, lines 5–19 (“A single continuous impulse is applied of between about 5 seconds to about 90 seconds, preferably between about 5 seconds and about 15 seconds”).

Claim 8 recites that the step of actuating the electrode to create an electrical field comprises the step of applying an impulse at a frequency of between about one Hertz and about five hundred Hertz. Claim 9 limits the frequency to 20–80 Hz, and Claim 10 recites a frequency of about 40 Hz. Support is found in the specification, *e.g.*, at page 8, lines 5–19 (“Impulse parameters can readily be varied, *e.g.*, a frequency range of between about 1Hz and

about 500Hz, preferably between about 20 Hz to about 80Hz, more preferably about 40 Hz).

Claim 11 recites that the duration of the pulse is 0.4 msec. Support is found in the specification at p. 10, lines 23–26 (“Vagal stimulation was performed with a nerve stimulator ... in the monopolar mode at a frequency of 40 Hz, an impulse duration of 0.4 msec, and an amplitude of 2–6 volts.”)

Claim 12 recites a voltage of 1–40 volts. Support is found in the specification, *e.g.*, at page 8, lines 5–19 (“Impulse parameters can readily be varied, e.g, a frequency range of between about 1Hz and about 500Hz, preferably between about 20 Hz to about 80Hz, more preferably about 40 Hz, with an amplitude between about 1 to about 40 volts.”) Claim 13 recites a voltage of 2–6 volts. Support for Claim 13 is found in the specification at p. 10, lines 23–26 (“Vagal stimulation was performed with a nerve stimulator ... in the monopolar mode at a frequency of 40 Hz, an impulse duration of 0.4 msec, and an amplitude of 2–6 volts.”)

Claim 14 recites a list of surgical procedures in conjunction with which vagal nerve stimulation can be used. The recited group consists of: minimally invasive direct coronary artery bypass graft surgery (support at p. 4, lines 7–8), off-pump coronary artery bypass graft surgery (p. 4, lines 10–11), coronary artery bypass surgery performed on cardiopulmonary bypass (p. 5, lines 33–35), partially or totally endoscopic coronary artery bypass graft surgery (p. 4, lines 11–12), percutaneous or surgical transmyocardial laser revascularization procedure (p. 4, lines 12–14), or a surgical procedure performed upon a heart, heart valves, myocardium, coronary vascular structure, peripheral vascular structure, a

electrophysiological procedure, a neurosurgical procedure, or a percutaneous transcatheter coronary procedure.

Claim 15 recites that the stimulation of the vagal nerve is effective to achieve asystole. Support for this limitation is found in the specification, *e.g.*, in FIG. 1, where asystole is shown to have been achieved in both the non-drug treated and drug treated state.

Claims 16–30 are similar to Claims 1–15, except the electrode(s) are positioned within the trachea. Support for this limitation is found, *e.g.*, at p. 8, lines 5–20 (“Other suitable locations for vagus nerve stimulation include ... stimulation with a percutaneous catheter or electrode probe in the internal jugular vein, esophagus, or trachea”).

Claims 31–45 are similar to Claims 1–15, except the electrode(s) are positioned within a jugular vein. Support for this limitation is found, *e.g.*, at p. 8, lines 5–20 (“Other suitable locations for vagus nerve stimulation include ... stimulation with a percutaneous catheter or electrode probe in the internal jugular vein”)

Claims 46–60 are similar to Claims 1–15, except the electrode(s) are positioned on the patient’s neck. Support for this limitation is found, *e.g.*, at p. 8, lines 5–20 (“Electrical stimulation is carried out on the right vagus nerve, preferably at a site on the neck. ”)

Claims 61–74 are similar to Claims 2–15, except that one electrode is positioned in the esophagus, and the second electrode is positioned in the trachea. Support for this limitation is found, *e.g.*, at p. 8, lines 5–20 (“Other suitable locations for vagus nerve stimulation include ... stimulation with a percutaneous catheter or electrode probe in the internal jugular vein, esophagus, or trachea, or combination of these.”).

Claims 75–88 are similar to Claims 2–15, except that one electrode is positioned in the esophagus, and the second electrode is positioned in a jugular vein. Support for this limitation is found, *e.g.*, at p. 8, lines 5–20 (“Other suitable locations for vagus nerve stimulation include ... stimulation with a percutaneous catheter or electrode probe in the internal jugular vein, esophagus, or trachea, or combination of these.”).

Claims 89–102 are similar to Claims 2–15, except that one electrode is positioned in the esophagus, and the second electrode is positioned on the neck. Support for this limitation is found, *e.g.*, at p. 8, lines 5–20 (“Electrical stimulation is carried out on the right vagus nerve, preferably at a site on the neck. Other suitable locations for vagus nerve stimulation include ... stimulation with a percutaneous catheter or electrode probe in the internal jugular vein, esophagus, or trachea, or combination of these.”).

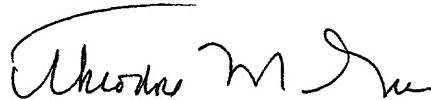
Claims 103–116 are similar to Claims 2–15, except that one electrode is positioned in the trachea, and the second electrode is positioned in the jugular vein. Support for this limitation is found, *e.g.*, at p. 8, lines 5–20 (“Other suitable locations for vagus nerve stimulation include ... stimulation with a percutaneous catheter or electrode probe in the internal jugular vein, esophagus, or trachea, or combination of these.”).

Claims 117–130 are similar to Claims 2–15, except that one electrode is positioned in the trachea, and the second electrode is positioned on the neck. Support for this limitation is found, *e.g.*, at p. 8, lines 5–20 (“Electrical stimulation is carried out on the right vagus nerve, preferably at a site on the neck. Other suitable locations for vagus nerve stimulation include ... stimulation with a percutaneous catheter or electrode probe in the internal jugular vein, esophagus, or trachea, or combination of these.”).

Claims 131–144 are similar to Claims 2–15, except that one electrode is positioned in the jugular vein, and the second electrode is positioned on the neck. Support for this limitation is found, e.g., at p. 8, lines 5–20 (“Electrical stimulation is carried out on the right vagus nerve, preferably at a site on the neck. Other suitable locations for vagus nerve stimulation include ... stimulation with a percutaneous catheter or electrode probe in the internal jugular vein, esophagus, or trachea, or combination of these.”).

Examination of the application at an early date is requested in view of the foregoing remarks.

Respectfully submitted:



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